

**Title**

Incidence of submacular haemorrhage (SMH) in Scotland: a Scottish Ophthalmic Surveillance Unit Study (SOSU) study

**Running Title**

Incidence of submacular haemorrhage (SMH) in Scotland: A SOSU study

**Corresponding Author**

Dr Aws Al-Hity  
Tennent Institute of Ophthalmology  
Gartnavel General Hospital  
1053 Great Western Road  
Glasgow  
G12 0YN  
Tel: 0141 211 1041  
Email: [alhitya@gmail.com](mailto:alhitya@gmail.com)

**Co-authors**

- Dr David H Steel  
Sunderland Eye Infirmary and IGM, Newcastle University  
[David.steel@newcastle.ac.uk](mailto:David.steel@newcastle.ac.uk)
- Dr David Yorston  
Tennent Institute of Ophthalmology  
[David.yorston@ggc.scot.nhs.uk](mailto:David.yorston@ggc.scot.nhs.uk)
- Dr David Gilmour  
Tennent Institute of Ophthalmology  
[David.gilmour@ggc.scot.nhs.uk](mailto:David.gilmour@ggc.scot.nhs.uk)
- Dr Zachariah Koshy  
University Hospital Ayr  
[Zachariah.koshy@aapct.scot.nhs.uk](mailto:Zachariah.koshy@aapct.scot.nhs.uk)
- Dr David Young  
Department of Mathematics and Statistics  
University of Strathclyde  
[David.young@strath.ac.uk](mailto:David.young@strath.ac.uk)
- Prof Jost Hillenkamp  
Kiel University, Germany  
[zese@ukw.de](mailto:zese@ukw.de)
- Dr Gerard McGowan  
Tennent Institute of Ophthalmology  
[Gmcgowan1@nhs.net](mailto:Gmcgowan1@nhs.net)

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## ABSTRACT

**Title:** Incidence of submacular haemorrhage (SMH) in Scotland: a Scottish Ophthalmic Surveillance Unit Study (SOSU) study

**Purpose:** Submacular haemorrhage is a cause of severe visual loss in neovascular age-related macular degeneration (nAMD). The incidence is uncertain and furthermore there is no widely-used classification system nor agreed best practice. The aim of this national surveillance study was to identify the incidence, presenting features and clinical course of new fovea-involving submacular haemorrhage associated with nAMD.

**Methods:** A questionnaire was sent monthly to every ophthalmic specialist in Scotland over a 12-month period asking them to report all newly presenting patients with acute SMH secondary to nAMD of at least 2 disc diameters (DD) in greatest linear diameter. A follow-up questionnaire was sent 6 months after initial presentation. Cases related to other causes were excluded.

**Results:** Twenty-nine cases were reported giving an incidence of 5.4 per million per annum (range 2-15). The mean age was 83 years (range 66-96) and females accounted for 17/29 (59%). 15/29 (52%) had a past history of AMD, of which 7 was nAMD. 19/29 (66%) presented within 7 days of onset and the majority had SMH of less than 11 DD (20/29,69%). Treatment options comprised: observation (n=6,21%), anti-VEGF alone (n=6,21%) or vitrectomy with co-application of tPA, anti-VEGF and gas (n=17,58%). The vitrectomy group experienced the greatest change in vision from logMAR 1.89 to 1.50 (p=0.374). 4/20 (20%) cases with 6 months follow up suffered a re-bleed at a mean time of 96 days.

**Conclusions:** The incidence, clinical features and course of a consecutive national cohort of patients with SMH secondary to nAMD are presented.

## INTRODUCTION

The prognosis for neovascular age-related macular degeneration (nAMD) has been transformed by the use of intravitreal anti-vascular endothelial growth factor (anti-VEGF) drugs. Some patients, however, still have poor outcomes. One cause of severe visual loss in nAMD is submacular haemorrhage (SMH). Although the incidence of SMH is ill-defined it is known to be relatively uncommon, and has a very poor prognosis untreated. (1)

The optimum treatment of wet AMD complicated by significant SMH is uncertain. To date, several studies have suggested that treatment with anti-VEGFs alone may be superior to observation whilst others have suggested that displacement of blood with gas and sub-retinal or intravitreal tPA and anti-VEGF may be more optimal. Identifying the incidence of this complication and its optimal treatment has obvious implications for public health and cost effectiveness. (2-8)

The best evidence to determine if these more invasive procedures really represent an advance over management with intravitreal anti-VEGF alone would be a randomised clinical trial (RCT). To assist the design of such a trial, data on the incidence, natural history and outcome of a consecutive series of non-selected patients presenting with SMH in the era of anti-VEGF treatment is needed. We therefore designed a prospective observational study in Scotland, UK. Specifically, we aimed to assess the incidence of SMH occurring secondary to nAMD, the clinical features at presentation, the treatment modalities currently being used and finally prognostic factors which could help in future decision making.

## METHODS

This was a nationwide, prospective observational study with active surveillance of cases through the Scottish Ophthalmological Surveillance Unit (SOSU) monthly reporting card scheme. SOSU has the same methodology as its sister organisation, the British Ophthalmological Surveillance Unit (BOSU) where several studies have been conducted previously. (9-13) Both were established to assist in the investigation of the incidence and clinical features of rare eye conditions of scientific and public health importance. The BOSU steering committee review all protocols of individual studies in order that certain basic criteria are met and to provide advice on the design of their questionnaires and studies. (14)

The SOSU surveillance scheme involves all consultant or associate specialist ophthalmologists with clinical autonomy in Scotland who form the reporting base. Ophthalmologists were asked to notify the study investigators, through the SOSU of all newly diagnosed cases of fovea-involving SMH of size greater than 2 DD. Case notifications were requested over the 12-month study period September 2013 to September 2014. All SMH not related to AMD were excluded.

Following case notification to the SOSU, every consultant ophthalmologist in Scotland was sent a detailed questionnaire by the study investigators requesting data on: visual acuity, lens status, fellow

eye status, duration of symptoms (recorded as 1-7, 8-14 and >14 days), previous treatment for SMH, size of haemorrhage (recorded in groups 2-6, 7-11, 12-16 and >16 disc diameters (DD)), past history of nAMD, ocular co-morbidities, time to treatment and initial management. Snellen visual acuity was converted to logMAR equivalent (6/6 being 0.00, 6/60 being 1.00). Vision worse than 6/60 (counting fingers and hand motions was ascertained using the Freiburg Visual Acuity Test (FrACT) and determined to be 2.0 and 2.3 respectively). (15) Outcome data were obtained from follow-up questionnaires sent to the reporting ophthalmologists 6 months after diagnosis (questionnaires available as supplementary material). Follow-up data collected comprised: subsequent treatment (within the 6-month follow up period), follow-up visual acuity and complications (re-bleed). Those who did not return questionnaires were sent repeat request letters at 2 and 3 months after the initial request had been sent. The response rate was calculated as the number of questionnaires received over the total reporting cards received. (14)

Statistical analysis was performed with presentation of mean or median and range as appropriate. Visual acuity was converted to logMAR for analysis and non-parametric multi-group tests (Wilcoxon) used to compare vision pre and post intervention. Non-parametric multi-group analysis was also performed to identify whether various risk factors (size of haemorrhage, duration of symptoms and nature of intervention) have an impact on visual acuity at 6-month follow up. A p value of less than 0.05 was considered significant.

#### *Incidence rate*

Scotland has been recognised in previous studies as a well-defined region with stable population demographics. (11,16) The proportion of the Scottish population of retirement age (65 years) has been shown to be relatively stable and representative of the whole UK population (18.0% vs 17.7%, respectively) and as such the Scottish population can be used as a focus population in a similar manner to previous studies. (11,16) The male to female ratio is 17:12. The incidence was calculated as the number of reported cases as a proportion of the total population over the 1-year study period the number of cases were also tracked to the source National Health Service (NHS) trust in order to calculate the incidence for each of the eight Scottish regions.

## **RESULTS**

Over the 12-month period between September 2013 and September 2014, a total of 29 reported cases and 29 initial questionnaires received giving a response rate of 100%. Six month follow up data was received on 20 of the 29 cases. The total Scottish population in 2013 was 5,327,700 giving an overall incidence of 5.4 per million per annum. (17) The incidence varied by region from 15 per million per annum in the Greater Glasgow and Clyde region (17 cases with a population of 1,137,000) to 2 per million per annum in the Grampian region (1 case with a population of 526,000) (Table 1). (18)

The baseline data are presented in Table 2. The mean age was 83 years with 17 (59%) females. Fifteen (52%) had a past history of AMD of which 7 was nAMD. A total of 19/29 (66%) presented

within 1-7 days of onset of symptoms. 7/29 (24%) presented greater than 2 weeks after onset of symptoms. Eleven (38%) had a SMH of size 7-11 DD while a further 9/29 (31%) were of size 2-6 DD.

#### *Treatment modalities*

There were 3 management strategies observed: observation, anti-VEGF agents alone (either ranibizumab or aflibercept) and vitrectomy and co-application of intra-vitreous or subretinal tPA/anti-VEGF (see Table 2). No cases with expansile gas and intravitreal tPA/ Anti-VEGF were reported either as initial treatment or subsequently.

#### *Visual acuity*

Overall, the mean visual acuity non-significantly improved from 1.85 at baseline to 1.61 ( $p=0.072$ ) with differences, again non-significant between the groups, but with the greatest effect seen in the vitrectomy group (1.89 to 1.50,  $p=0.374$ ). The eligibility for treatment in the UK NHS is dependent on being better than the UK National Institute of Clinical Excellence (NICE) visual acuity cut off of 25 ETDRS letters (1.20 logMAR) or better. Of the 29 cases, 6 (20.7%) met these criteria at baseline. This percentage rose to 35.0% (7/20) at follow-up. Subsequent treatment was given in 13/20 (65.0%) of cases, all receiving intravitreal ranibizumab. The mean number of injections given was 2 (range 1-6).

#### *Duration of symptoms*

Those presenting within the median of 1-7 days of onset of symptoms showed a mean improvement in visual acuity from 1.76 to 1.37 ( $p=0.27$ ). However, the duration of symptoms was not a significant predictor of visual acuity at 6-month follow up ( $p=0.381$ ).

#### *Size of haemorrhage*

The median size of SMH was 7-11 DD. There were no significant differences in baseline and follow up between any of the groups but the greatest improvement was seen in the smallest SMH size group of 2-6 DD ( $p=1.00$ ). In contrast, a decline in mean visual acuity was seen in haemorrhages of greater than 16 DD (see Table 4).

#### *Complications*

A total of 4/20 (20%) suffered re-bleeds with a mean time of 96 days (range 52-170) from the date of treatment. One case was in the observation group while the other 3 were in the surgical group. The mean visual acuity in this group improved from 1.95 to 1.77 despite the rebleed. Three out the 4 (75%) were treated with subsequent anti-VEGF.

## DISCUSSION

In this study, we present data from a national surveillance study into all cases of acute submacular haemorrhage over a 12-month period in Scotland. Through this prospective study, we have identified an incidence rate of fovea-involving submacular haemorrhage of 5.4 per million per annum. It was noted on postcode data that the incidence varied greatly by region ranging from 15 per million to 2 per million per annum. There are a number of reasons for these variations. The first may be a degree of under-reporting which is evident in any surveillance scheme, although the response rate from participating ophthalmologists in the BOSU scheme has been consistently more than 70%. (14) Secondly, patients may fail to present due to access to healthcare. For example, NHS Highland covers an estimated area of 12,500 square miles and serves a population of 320,000. (18) In contrast to this, NHS Greater Glasgow and Clyde has a population of 1,137,000 and 17 reported cases (incident rate of 15 per million per annum). With an area of 452 square miles, the population density of Glasgow and Clyde is much higher than NHS Highland at 2,515 people per square mile, compared to just 26 people per square mile. (18) This might have contributed to the variations in reporting rates. One can also suppose that these differences across regions are genuine, however this was not seen in a pilot study which showed comparable incidence rates between Sunderland and Glasgow (24 per million per annum) although these are very comparable areas in terms of population density, healthcare provision and deprivation indices. (8)

In our study, those that were observed showed a slight decline in visual acuity whilst those who were treated surgically showed a non-significant improvement in visual acuity. Patients treated with anti-VEGF agents alone resulted in maintained and in certain cases, improved visual outcomes compared to the natural history of the submacular haemorrhage which concurs with previous reports. (2,4,19-23) There appears to be a delay in treatment time when patient is managed non-surgically as compared to surgically. This may reflect the improvement in visual acuity when looking at the surgical group versus non-surgical group. This limitation of the study means that robust comparisons between surgical and non-surgical groups cannot be inferred. The pressures of service delivery, especially in the National Health service, mean that it is often days or weeks until patients are seen, have the appropriate diagnostic investigations, a management plan is arranged and executed. Strategies to highlight time sensitive conditions such as SMH must be in place if severe visual loss is to be prevented. There were no reported cases of the use of pneumatic displacement with intravitreal tPA although this has been widely reported as an effective strategy combined with anti VEGFs previously. (19-21,24,25) Having said this, the relative efficacy of expansile gas and intravitreal TPA compared to vitrectomy with subretinal TPA and air or gas is uncertain. A recent randomised controlled trial showed no difference in results between the two modalities but previous studies have shown a higher efficacy of subretinal TPA over intravitreal TPA in terms of displacement of blood eccentrically to fovea. (26,27) A study of vitrectomy combined with subretinal TPA and air reported 3 cases that were successfully displaced that had previously failed to displace with expansile gas and intravitreal TPA and the vitrectomy technique may offer advantages in patients unable to posture. (5) It appears that in Scotland displacement with the expansile is not popular which may be due to a variety of possible

reasons including personal surgical preference, patient choice and the lack of ability, or perceived risks of posturing in the age group affected. (25)

The evidence base for the treatment of SMH associated with AMD largely comprises case-series which tend to focus on surgeon-selected cases and a variety of criteria to guide individual treatment choices. Therapeutic decision-making is difficult due to a lack of standardisation in both the classification of SMH and outcome reporting. (28) The strength of this study is that we report on the presentation and management of all cases over a one-year period with 6-month follow data to give a true picture of the cases seen in clinical practice and real world outcomes from a range of management options and which we hope will help guide the design of a future randomised controlled trial. There are however several limitations to the study, including the lack of access to fundal imaging to ascertain the precise features of the haemorrhages and absence of protocol refracted visual acuities. Follow up was also limited to 6 months and incomplete.

In conclusion, this prospective national surveillance study has identified an incidence for submacular haemorrhage of 5.4 per million per annum but with a wide range of 2-15. It is hoped that this surveillance study will inform future randomised control studies. In particular, further studies are indicated to clearly define the role of surgical intervention as compared to anti VEGF treatment alone in the treatment of fovea-involving submacular haemorrhage.

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Trust of reported cases	Population estimate	Cases	Incidence
NHS Greater Glasgow and Clyde	1,137,000	17	15.0
NHS Ayrshire and Arran	400,000	3	7.5
NHS Tayside	415,000	2	4.8
NHS Lothian	800,000	3	3.8
NHS Forth Valley	281,000	1	3.6
NHS Highland	320,000	1	3.1
NHS Fife	359,000	1	2.8
NHS Grampian	526,000	1	1.9

Table 1 Reported cases and incidence per regional Scottish NHS trusts (17)

Age, years (mean, range)	83, 66-96
Sex n (%)	
Female	17 (59%)
Male	12 (41%)
Visual acuity, logMAR (mean, range)	1.85, 0.8-2.3
Fellow eye visual acuity	0.94, 0.2-2.3
Duration of symptoms, Days n(%)	
1-7	19 (66%)
8-13	3 (10%)
>14	7 (24%)
Size of SMH, DD n(%)	
2-6	9 (31%)
7-11	11 (38%)
12-16	3 (10%)
>16	6 (21%)
Known ocular co-morbidity of affected eye n(%)	
None	13 (45%)
Dry AMD	8 (28%)
nAMD	7 (24%)
OHT	1 (3%)
Lens status n(%)	
Phakic	20 (69%)
Pseudophakic	9 (31%)
Initial treatment n (%)	
Observation	6 (21%)
IVT aflibercept	1 (3%)
IVT ranibizumab	5 (17%)
PPV/ SRET tPA & ranibizumab/ Gas	17 (58%)
Time to treatment (days) Mean (range)	
Anti-VEGF	38 (6-55)
Vitrectomy	3 (0-6)
Overall	10 (0-55)

Table 2 Clinical features at baseline. [VA;Visual acuity, SMH;submacular haemorrhage, DD;disc diameter, AMD;age related macular degeneration, nAMD;neovascular age related macular degeneration, PPV;Pars Plana Vitrectomy, IVT; Intravitreal, SRET;sub retinal]. N=29 for all values.

Subsequent treatment (anytime within the 6-month follow up period) n (%)	7 (35%)
None	13 (65%)
IVT ranibizumab	
6-month visual acuity (mean, range)	1.61, 0-2.3
6-month visual acuity fellow eye (mean, range)	0.91, 0-2.3
Re-bleed n (%)	4 (20%)
Sight impairment registration n (%)	
None	10 (50%)
Sight impairment	5 (25%)
Severe sight impairment	3 (15%)
Not known	2 (10%)

**Table 3** Follow-up data (VA;visual acuity, IVT;intravitreal). N=20 for all values)

Size of SMH (DD)	n	Baseline VA			Final VA			Change in VA	p value
		VA	SD	Range	VA	SD	Range		
2 - 6	9	1.51	0.48	1.04 - 2.00	1.21	0.26	1.14 - 1.5	-0.3	1.00
7 - 11	11	1.8	0.6	0.8 - 2.30	1.73	0.89	0.50 - 3.00	-0.07	0.855
12 - 16	3	2.2	0.17	2.00 - 2.30	2.15	0.21	2.00 - 2.30	-0.05	1.00
> 16	6	1.74	0.6	1.00 - 2.30	1.78	0.56	0.8 - 2.30	0.04	0.787

Table 4 Changes in visual acuity with different size of Submacular haemorrhage. VA;visual acuity, SD;standard deviation, DD;disc diameters